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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
REIDEL, JESSICA L	

ART UNIT	PAPER NUMBER
3766	

DATE MAILED: 02/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

C

Office Action Summary	Application No.	Applicant(s)	
	10/669,170	KENKNIGHT ET AL.	
	Examiner	Art Unit	
	Jessica L. Reidel	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 September 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *04/18/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on April 18, 2005 is acknowledged and is being considered by the Examiner.

Specification

2. The disclosure is objected to because of the following informalities: subject headings should not be underlined. In addition there appears to be a typographical error at page 6, lines 10-11. The Examiner suggests changing lines 6-7 from "ring electrodes 34a-d and tip electrodes 33a-d" to "ring electrodes 33a-d and tip electrodes 34a-d" to ensure consistency with Applicant's Figure 1. Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-2, 9-12, and 19-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Ding (U.S. 2002/0062139). As to Claims 1 and 11, Ding discloses an implantable device for delivering cardiac function therapy to a patient (see Ding Fig. 1 and page 2, paragraph 14) comprising atrial and ventricular sensing channels for sensing cardiac electrical activity at a plurality of myocardial sites and atrial and ventricular pacing channels for delivering pacing pulses to a plurality of myocardial sites (see Ding Fig. 1 and page 2, paragraph 15) and a controller 28 made up of a microprocessor 10 communicating with memory 12 and dedicated

circuitry for delivering pacing pulses in accordance with a programmed pacing mode (i.e. DDD, DVI, VDD, biventricular or multi-site ventricular pacing) with a defined pulse output sequence and pulse output configuration (see Ding page 2, paragraphs 11 and 14 and page 3, paragraph 16). Ding also discloses that the controller 28 is programmed to temporarily suspend delivery of cardiac function therapy, asses the patient's cardiac function (i.e. monitor changes in the condition of the heart's conduction system by measuring changes in ventricular activation patterns as reflected by electrogram signals detected from different locations in the heart) (see Ding page 1, paragraphs 6-7), and either re-initiate or continue the delivery of cardiac function therapy based upon the cardiac function assessment (see Ding Figs. 2-3, page 2, paragraphs 7 and 11 and page 3, paragraphs 16-17). Specifically, the pacing therapy of Ding "may be adjusted accordingly" in view of the cardiac function assessment (see Ding page 3, paragraph 16).

5. As to Claims 2 and 12, Ding disclose that the ventricular electrodes could be disposed in each of the ventricles for biventricular pacing or in only one ventricle for multi-site pacing of that ventricle (see Ding page 2, paragraph 15). It is inherent that a multi-site ventricular pacing improves the patient's cardiac pumping performance. In addition, Ding discloses the invention is directed towards those devices seeking to improve cardiac output and ventricular synchrony (see Ding page 1, paragraph 3).

6. As to Claims 9 and 19, Ding discloses that the controller 28 may be programmed to temporarily suspend delivery of cardiac function therapy (i.e. pacing) and asses the patient's cardiac function (i.e. changes in the condition of the heart's conduction system) upon a command

from an external programmer via telemetry interface 40 (see Ding page 2, paragraphs 13-14 and page 3, paragraph 16 and Claim 5).

7. As to Claims 10 and 20, Ding discloses that the assessment of cardiac function (i.e. calculating and storing conduction delays) may be accomplished at periodic intervals (see Ding page 2, paragraphs 10 and 12-13 and page 3, Claim 3).

8. Claims 1-2, 7, 10-12, 17 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Darvish et al. (U.S. 6,292,693) (herein Darvish). As to Claims 1, 10-11 and 20, Darvish discloses an implantable device 70 for delivering cardiac function therapy to a patient (see Darvish Fig. 6, column 1, lins 13-16 and column 7, lines 62-64) comprising sensing channels and pacing channels for sensing cardiac electrical activity at a plurality of myocardial sites and delivering pacing pulses to a plurality of myocardial sites (i.e. right atrium 28, right ventricle 30 and left ventricle 44) (see Dravish Figs. 1 and 6, column 4, lines 42-53 and column 5,lines 1-16). Device 70 also comprises a control logic unit, read as a controller 72 to control the application of electrical energy from electrodes 32, 34 and 46 (see Darvish column 7, lines 65-67) via an algorithm stored in memory 78 (see Darvish column 8, lines 60-64) which defines the pulse output sequence and pulse configuration for delivering cardiac function therapy (see Darvish column 5, lines 1-39). In reference to Darvish Fig. 3, the algorithm programmed into the controller 72 is depicted in flow chart form where the device 70 operates first in a cardiac function therapy (DDI pacing) mode (see Darvish column 6, lines 21-23), periodically assesses the patient's cardiac output, read as assessing the patient's cardiac function, and re-initiates or continues the delivery of cardiac function therapy based upon the cardiac function assessment (see Darvish Fig. 3). It is inherent that pacing is suspended during the assessment of the

patient's cardiac function since Darvish also discloses that the flow chart depicted in Fig. 3 is a "graduated application" to limit the electrical power that must be applied to the heart to prolong battery life and that the algorithm allows the heart muscle "to function in a natural manner as physiological needs will allow and to rest when enhanced cardiac output is not required" (see Darvish column 6, lines 7-20).

9. As to Claims 2 and 12, Darvish discloses that the cardiac function therapy may be bi-ventricular pacing, read as multi-site ventricular pacing or "any pacing mode known in the art" (see Darvish column 2, lines 48-54 and column 6, lines 24-29).

10. As to Claims 7 and 17, Darvish discloses that the cardiac function assessment may include measuring the patient's heart rate variability, which is inherently deterministic of a patient's autonomic balance since heart rate and variations of heart rate are products of both chains of a person's autonomic nervous system (see Darvish column 6, lines 35-41).

11. Claims 4, 6, 14 and 16 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Darvish. As to Claims 4 and 14, Darvish discloses that cardiac output is assessed to be "adequate" via a signal acquired by a physiological sensor sent to controller 72 (see Darvish column 4, lines 1-14). It is inherent or at least obvious to one having ordinary skill in the art that a determination of a signal being "adequate" is accomplished via a microprocessor 74 within controller 72, which compares the sensed signal to a specified threshold value.

12. As to Claims 6 and 16, Darvish discloses that the controller 72 may regulate the pacing algorithm depicted in Fig. 3 responsive to a subject's physical activity by utilizing an accelerometer, read as an exertion level sensor 104 (see Darvish column 9, lines 23-32). It is

inherent or at least obvious to one having ordinary skill in the art to compare the output of such exertion level sensor to an exertion level threshold to determine if the pacing algorithm should be modulated or not. Darvish also discloses that cardiac output is assessed to be "adequate" via a signal acquired by a physiological sensor sent to controller 72 (see Darvish column 4, lines 1-14). It is also inherent or at least obvious to one having ordinary skill in the art that a determination of a signal being "adequate" is accomplished via a microprocessor 74 within controller 72, which compares the sensed signal to a specified threshold value.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. Claims 3 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ding in view of Pastore et al. (U.S. 6,965,797) (herein Pastore).

The applied reference has a common Assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the

application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Ding discloses the claimed invention as discussed above except that the multi-site ventricular pacing is not specified to pre-excite selected myocardial regions in order to redistribute myocardial wall stress during systole for the purpose of ventricular remodeling. Pastore, however, disclose a device (see Pastore Fig. 1) which employs a cardiac function therapy of multi-site ventricular pacing to pre-excite selected myocardial regions in order to redistribute myocardial wall stress during systole for the purpose of ventricular remodeling (see Pastore column 2, lines 55-60, column 3, lines 1-4 and 29-42 and column 6, lines 55-67). The Examiner considers the device of Pastore to be synonymous with the device of Ding since both devices are concerned with improving a patient's cardiac output and providing cardiac resynchronization therapy through multi-site ventricular pacing (see Pastore column 1, lines 14-17 and 41-53 and column 7, lines 4-6). Therefore, it would have been obvious to one having ordinary skill in the art to modify the multi-site pacing of Ding in view of Pastore to pre-excite selected myocardial regions in order to redistribute myocardial wall stress during systole for the purpose of ventricular remodeling for increased cardiac output and cardiac resynchronization therapy.

15. Claims 3 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Darvish in view of Pastore et al. (U.S. 6,965,797) (herein Pastore).

The applied reference has a common Assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Darvish discloses the claimed invention as discussed above except that the multi-site ventricular pacing is not specified to pre-excite selected myocardial regions in order to redistribute myocardial wall stress during systole for the purpose of ventricular remodeling. Pastore, however, disclose a device (see Pastore Fig. 1) which employs a cardiac function therapy of multi-site ventricular pacing to pre-excite selected myocardial regions in order to redistribute myocardial wall stress during systole for the purpose of ventricular remodeling (see Pastore column 2, lines 55-60, column 3, lines 1-4 and 29-42 and column 6, lines 55-67). The Examiner considers the device of Pastore to be synonymous with the device of Darvish since both devices are concerned with improving a patient's cardiac output and providing cardiac

resynchronization therapy through multi-site ventricular pacing (see Pastore column 1, lines 14-17 and 41-53 and column 7, lines 4-6). Therefore, it would have been obvious to one having ordinary skill in the art to modify the multi-site pacing of Darvish in view of Pastore to pre-excite selected myocardial regions in order to redistribute myocardial wall stress during systole for the purpose of ventricular remodeling for increased cardiac output and cardiac resynchronization therapy.

16. Claims 5 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Darvish in view of Burnes (U.S. 2004/0220636). Darvish discloses the claimed invention as discussed above except that the physiological sensor for assessing the patient's cardiac output is not specified to be a trans-thoracic impedance measuring circuit.

Burnes, however, teaches that it is well known to provide an assessment of cardiac output of a patient by using an impedance monitor 162 that that measures transthoracic impedance (see Burnes Fig. 4, page 3, paragraph 29 and page 7, paragraphs 64-65). Burnes does not explicitly state why impedance monitor 162 is used, but it appears that impedance monitor 162 is used to provide a means to asses a patient's cardiac output external to or implanted within the body of a patient (see Burnes page 2, paragraph 15). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system and method as taught by Darvish, with the transthoracic impedance measuring circuit 162 as taught by Burnes, since such a modification would provide the system and method with a transthoracic impedance measuring for providing a means for cariac output to be assessed both internally and externally.

17. Claims 8 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Darvish in view of Zhu et al. (U.S. 2002/0120306) (herein Zhu). Darvish discloses the claimed invention

as discussed above except that the method carried out by device 70 does not comprise circuitry for measuring and collecting time intervals between successive chamber senses and storing the collected intervals as a discrete RR interval signal, filtering the RR interval signal into defined high and low frequency bands, and determining the signal power of the RR interval signal in each of the low and high frequency bands, referred to LF and HF, respectively, and, circuitry for computing an LF/HF ratio and assessing cardiac function by comparing the LF/HF ratio to a specified ratio threshold value.

Zhu, however, discloses that the LF/HF ration is a good indicator of the state of autonomic balance of a patient and discloses circuitry for measuring and collecting time intervals between successive chamber senses, storing the collected intervals as a discrete RR interval signal, filtering the RR interval signal into defined high and low frequency bands, and determining the signal power of the RR interval signal in each of the low and high frequency bands, and computing an LF/HF ratio and triggering a diagnostic mode of the device when the LF/HR exceeds a predetermined ratio threshold value (see Zhu page 5, paragraphs 39-41). It would have been obvious to one having ordinary skill in the art to modify the method and system of Darvish in view of Zhu to comprise circuitry for measuring and collecting time intervals between successive chamber senses and storing the collected intervals as a discrete RR interval signal, filtering the RR interval signal into defined high and low frequency bands, and determining the signal power of the RR interval signal in each of the low and high frequency bands, referred to LF and HF, respectively, and, circuitry for computing an LF/HF ratio and assessing cardiac function by comparing the LF/HF ratio to a specified ratio threshold value to acquire means to switch the device from a therapy mode to a diagnostic mode when necessary.

Conclusion

18. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. It appears that DeGroot (U.S. 6,167,308) anticipates or at least renders obvious Claims 1-3 and Claims 10-13. DeGroot teaches that it is well known in the art to temporarily suspend a pacing regimen, read as a cardiac function therapy, asses the patient's cardiac function (i.e. determine of the patient's heart has returned to normal sinus rhythm) and re-initiate or continue delivery of the cardiac function therapy (i.e. pacing) based upon the cardiac function assessment. It also appears that Ding (U.S. 6,424,865) anticipates or at least renders obvious Claims 1-3, 9-13 and 19-20.

Kramer et al. (U.S. 6,628,988) teaches that multi-site ventricular pacing can be used to pre-excite selected myocardial regions in order to redistribute myocardial wall stress during systole for the purpose of reversing ventricular remodeling.

Nappholz et al. (U.S. 5,183,040) discloses an anti-tachycardia pacer and pacing method, which optimizes the pacing regimen by taking cardiac output measurements using an ultrasonic sensor.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica L. Reidel whose telephone number is (571) 272-2129. The examiner can normally be reached on Mon-Thurs 7-4:30 and every other Friday 7-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jessica L. Reidel 02/20/06
Examiner
Art Unit 3766

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